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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,641	08/04/2003	Kyoya Takahata	TECH-004	7194

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,641	TAKAHATA, KYOYA	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-14* is/are rejected.

7)☒ Claim(s) *3 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claims 1-14 are presented for prosecution on the merits.

Abstract

The abstract of the disclosure is objected to because it is not limited to a single paragraph. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement(s)

Applicant's Information Disclosure Statement received April 22, 2004 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Objection(s)

Claim 11 is objected to because of the following informalities: in claim 11, line 1, after "administering", there is no patient or subject described. The Examiner respectfully submits adding language such as –to a patient in need thereof--. Appropriate correction is required.

Claim Rejection(s)—35 USC 112/101

1. Claims 13-14 provide for the use of the claimed N-vanillyl fatty acid amide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The claims will be interpreted as methods of making a medicament.

Claim Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

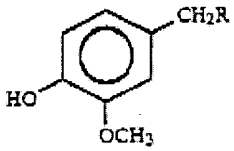
2. Claims 1-2, 5, 9-14 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Jin et al. (abstract only).

Jin et al. disclose a newly synthesized compound dohevanil, wherein tests demonstrate that dohevanil has potent inhibitory effects against HeLa cells and taxol-resistant HeLa cells. Please see the abstract.

3. Claims 1-2, 5-6, 7-8, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Janusz et al. (journal) or Janusz et al., 4,898,887.

Janusz et al. (journal) teach vanillamine amide compounds which read on Applicant's claims. Please see for example Table I, compound 10. The compounds are formulated into compositions for systemic administration. Please see the abstract; page 2596, 1. Antinociceptive Assays.

Janusz et al. ('887) discloses trienamide and tetraenamide compounds of the disclosed formula,



wherein R is a straight or branched chain tri-unsaturated or tetra-unsaturated fatty acid amide having from 14 to 24 carbon atoms. Preferred compounds are:

Preferred trienamides include those wherein R is derived from such cis-triunsaturated fatty acids as 11Z,14Z,17Z-eicosatrienoic acid, γ-linolenic acid, and linolenic acid. Preferred tetraenamides include those wherein R is derived from such cis-tetraunsaturated fatty acids as arachidonic acid, and thus the particularly preferred tetraenamide of the present invention is N-vanillyl-5Z,8Z,11Z,14Z-eicosatetraenamide (i.e., N-vanillylarachidonamide). Particularly preferred trienamides include N-vanillyl-9Z,12Z,15Z-octadecatrienamide (N-vanillyl-linolenamide), N-vanillyl-6Z,9Z,12Z-octadecatrienamide (N-vanillyl-γ-linolenamide), and N-vanillyl-11Z,14Z,17Z-eicosatrienamide. The most preferred trienamide for anti-inflammatory activity is N-vanillyl-6Z,9Z,12Z-octadecatrienamide. The most preferred trienamide for analgesic activity is N-vanillyl-11Z,14Z,17Z-eicosatrienamide, which appears to have analgesic activity comparable to that of the opioids, but does not exhibit undesirable narcotic side effects. Preferred pharmaceutically-acceptable trienamide and tetraenamide salts include the sodium, potassium, calcium, magnesium, and ammonium salts.

The compounds are formulated into compositions for reducing inflammation and producing analgesics. Please see the abstract; col. 3, lines 1-65.

4. Claims 1-2, 5-6, 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Martin et al., 2004/0122089.

Martin et al. teach the medicament arvanil, which is a potent anti-proliferative agent for human breast cancer cells. Please see [0008].

5. Claims 1-2, 5-7, 13-14 rejected under 35 U.S.C. 102(b) as being anticipated by Chen 5,221,692.

Chen discloses a novel pharmaceutical named olvanil which is an anti-inflammatory analgesic agent with high oral ED50 of 170mg/kg. Please see col. 1, lines 55-58.

6. Claims 1-2, 5, 9-10,13-14 rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Takahata et al. abstract only.

Takahata et al. disclose the compound dohevanil, which has anti-tumor properties by inducing cancer cell apoptosis. Please see the abstract.

With respect to the claimed intended use of claims 1-2 and 13-14, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully submits that the prior art compounds, which anticipate the claims, are capable of use as anti-tumor or anti-melanoma agents. Furthermore, with respect to claims 13-14, the intended use of treating tumors is of no significance to the process of manufacturing the medicament.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al., supra .

Martin et al. as applied above.

Martin et al. does not specifically disclose administering arvanil to treat a tumor; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer arvanil to a patient suffering from a tumor such as breast cancer because in view of the anti-proliferative properties of arvanil, one of ordinary skill in the art would reasonably expect arvanil to effectively treat a patient suffering from breast cancer.

8. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahata et al., supra.

Takahata et al. as applied above.

Takahata et al. do not specifically disclose administering dohevanil to a patient for treating a tumor ; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use dohevanil therapeutically because, based on the compound's ability to induce apoptosis in cancer cells, one of ordinary skill in the

art would reasonably expect dohevanil, when administered to a patient in need thereof, to induce apoptosis of tumors such as leukemia or melanomas.

Claims 3-4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-2, 5-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Oct. 1, 2004

Cybille Delacroix-Muirheid
Patent Examiner Group 1600